

(iv) “[Bullet] you have tremors, nervousness, or seizure”.

(d) *Directions*. The labeling of the product contains the following information under the heading “Directions”:

(1) *For products containing ephedrine, ephedrine hydrochloride, ephedrine sulfate, or racephedrine hydrochloride identified in § 341.16(a), (b), (c), and (f)*: (i) “[Bullet] do not take more than directed” [sentence appears as first bulleted statement under “Directions” and in bold type]

(ii) “[Bullet] adults and children 12 years of age and over: oral dose is 12.5 to 25 milligrams every 4 hours as needed. Do not take more than 150 milligrams in 24 hours”.

(iii) “[Bullet] children under 12 years of age: ask a doctor”.

(2) *For products containing epinephrine, epinephrine bitartrate, and racepinephrine hydrochloride identified in § 341.16(d), (e), and (g) for use in a hand-held rubber bulb nebulizer*. The ingredient is used in an aqueous solution at a concentration equivalent to 1-percent epinephrine:

(i) “[Bullet] do not use more than directed” [appears as first bulleted statement under “Directions” and in bold type].

(ii) “[Bullet] adults and children 4 years of age and over: 1 to 3 inhalations not more often than every 3 hours. Do not use more than 12 inhalations in 24 hours. The use of this product by children should be supervised by an adult.”

(iii) “[Bullet] children under 4 years of age: ask a doctor”.

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§ 341.78 Labeling of expectorant drug products.

(a) *Statement of identity*. The labeling of the product contains the established name of the drug, if any, and identifies the product as an “expectorant.”

(b) *Indications*. The labeling of the product states, under the heading “In-

dications,” the following: “Helps loosen phlegm (mucus) and thin bronchial secretions to” (select one or more of the following: “rid the bronchial passageways of bothersome mucus,” “drain bronchial tubes,” and “make coughs more productive”). Other truthful and nonmisleading statements, describing only the indications for use that have been established and listed in this paragraph (b), may also be used, as provided in § 330.1(c)(2) of this chapter, subject to the provisions of section 502 of the act relating to misbranding and the prohibition in section 301(d) of the act against the introduction or delivery for introduction into interstate commerce of unapproved new drugs in violation of section 505(a) of the act.

(c) *Warnings*. The labeling of the product contains the following warnings, under the heading “Warnings”:

(1) “A persistent cough may be a sign of a serious condition. If cough persists for more than 1 week, tends to recur, or is accompanied by a fever, rash, or persistent headache, consult a doctor.”

(2) *For expectorant drug products labeled for adults or for adults and children under 12 years of age*. “Do not take this product for persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema, or where cough is accompanied by excessive phlegm (mucus) unless directed by a doctor.”

(3) *For expectorant drug products labeled only for children under 12 years of age*. “Do not give this product for persistent or chronic cough such as occurs with asthma or if cough is accompanied by excessive phlegm (mucus) unless directed by a doctor.”

(d) *Directions*. The labeling of the product contains the following information under the heading “Directions” for products containing guaifenesin identified in § 341.18: Adults and children 12 years of age and over: oral dosage is 200 to 400 milligrams every 4 hours not to exceed 2,400 milligrams in 24 hours. Children 6 to under 12 years of age: oral dosage is 100 to 200 milligrams every 4 hours not to exceed 1,200 milligrams in 24 hours. Children 2 to under 6 years of age: oral dosage is 50 to 100 milligrams every 4 hours not to exceed 600 milligrams in 24 hours. Children under 2 years of age: consult a doctor.

(e) The word “physician” may be substituted for the word “doctor” in any of the labeling statements in this section.

[54 FR 8509, Feb. 28, 1989, as amended at 57 FR 29177, June 30, 1992]

§ 341.80 Labeling of nasal decongestant drug products.

(a) *Statement of identity.* The labeling of the product contains the established name of the drug, if any, and identifies the product as a “nasal decongestant.”

(b) *Indications.* The labeling of the product states, under the heading “Indications,” the phrase listed in paragraph (b)(1) of this section, as appropriate, and may contain any additional phrases listed in paragraph (b)(2) of this section. Other truthful and non-misleading statements, describing only the indications for use that have been established and listed in paragraphs (b)(1) and (b)(2) of this section, may also be used, as provided in § 330.1(c)(2) of this chapter, subject to the provisions of section 502 of the Federal Food, Drug, and Cosmetic Act (the act) relating to misbranding and the prohibition in section 301(d) of the act against the introduction or delivery for introduction into interstate commerce of unapproved new drugs in violation of section 505(a) of the act.

(1) (Select one of the following: “For the temporary relief of nasal congestion” or “Temporarily relieves nasal congestion”) (which may be followed by any of the following in paragraphs (b)(1) (i), (ii), and (iii) of this section):

(i) “due to” (select one of the following: “the common cold” or “a cold”).

(ii) “due to” (select one of the following: “hay fever,” “hay fever (allergic rhinitis),” “hay fever or other upper respiratory allergies,” or “hay fever or other upper respiratory allergies (allergic rhinitis)”).

(2) In addition to the information identified in paragraph (b)(1) of this section, the labeling of the product may contain any (one or more) of the following statements:

(i) (Select one of the following: “For the temporary relief of” or “Temporarily relieves”) (select one of the following: “stuffy nose,” “stopped up

nose,” “nasal stuffiness,” or “clogged up nose.”)

(ii) (Select one of the following: “Reduces swelling of,” “Decongests,” or “Helps clear”) “nasal passages; shrinks swollen membranes.”

(iii) “Temporarily restores freer breathing through the nose.”

(iv) “Helps decongest sinus openings and passages; temporarily relieves sinus congestion and pressure.”

(v) “Promotes nasal and/or sinus drainage; temporarily relieves sinus congestion and pressure.”

(c) *Warnings.* The labeling of the product contains the following warnings under the heading “Warnings”:

(1) *Oral nasal decongestants*—(i) *For products containing phenylephrine hydrochloride, pseudoephedrine hydrochloride, pseudoephedrine sulfate, or phenylephrine bitartrate identified in § 341.20 (a)(1) through (a)(4) when labeled for adults.* (A) “Do not exceed recommended dosage. [first sentence in boldface type] If nervousness, dizziness, or sleeplessness occur, discontinue use and consult a doctor.”

(B) “If symptoms do not improve within 7 days or are accompanied by fever, consult a doctor.”

(C) “Do not take this product if you have heart disease, high blood pressure, thyroid disease, diabetes, or difficulty in urination due to enlargement of the prostate gland unless directed by a doctor.”

(D) *Drug interaction precaution.* “Do not use if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional conditions, or Parkinson’s disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.”

(ii) *For products containing phenylephrine hydrochloride, pseudoephedrine hydrochloride, pseudoephedrine sulfate, or phenylephrine bitartrate identified in § 341.20 (a)(1) through (a)(4) when labeled for children under 12 years of age.* (A) “Do not exceed recommended dosage. [first sentence in boldface type] If nervousness, dizziness, or sleeplessness occur, discontinue use and consult a doctor.”